IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventor	**:**	**David Becker et al.**
Application No.	**:**	**10/599,306**
Filed	**:**	**September 25, 2006**
For	**:**	**ULTRASONIC INTRACAVITY PROBE FOR 3D IMAGING**

APPEAL BRIEF

On Appeal from Group Art Unit 3768
Examiner Vani Gupta

W. Brinton Yorks, Jr.

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
22100 Bothell Everett Highway
Bothell, WA 98021
Phone: (425) 487-7152
Fax: (425) 487-8135
email: brint.yorks@philips.com

Attorney for Appellant

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands by virtue of an assignment recorded September 25, 2006 at reel 018299, frame 0205.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

This application was originally filed with Claims 1-20. Following several Office actions and the cancellation of Claim 3, Claims 1-2 and 4-20 now stand finally rejected by an Office action mailed on July 19, 2010. A Notice of Appeal was timely filed on September 15, 2010. The claims being appealed are Claims 1-2 and 4-20.

IV. STATUS OF AMENDMENTS

No amendments were filed in response to the final rejection mailed July 19, 2010.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Ultrasound probes which are to be inserted into a body cavity to scan organs of the urinary or reproductive systems are configured with a handle and the ultrasound transducer located at the end of an elongated shaft. The transducer can scan the interior of the body in one of two ways: either electronic steering of beams from a fixed transducer or mechanical sweeping of a movable transducer. The present invention is a mechanically swept probe, in which a motor in the handle actuates a drive mechanism to mechanically sweep a pivotally mounted array transducer located at the distal end of the probe. For mechanically swept probes, the transducer must be located in a liquid-filled compartment which permits transducer movement while coupling ultrasound energy between the body and the transducer. Ultrasound at diagnostic imaging frequencies does not travel through air. A problem with such probes is that the fluid compartment can be sizeable, extending at times into the shaft of the probe. A sizeable fluid compartment must be filled with a substantial amount of fluid which has weight, and is located at the distal end of the probe. The distally-located weight of the transducer assembly and liquid causes the center of gravity of the probe to be located forward of the handle, which adversely affects manipulation and use of the probe. The present invention overcomes this difficulty by constraining the fluid to a

rigidly dimensioned transducer mount compartment at the distal end of the shaft, with only a small volume compensation balloon extending into the shaft behind the transducer assembly. Constraining the fluid in this manner causes the center of gravity of the probe to be located in the handle, which enables easier manipulation and use of the probe.

Comparing independent Claim 1 to the drawings and specification, it is seen that the claim is supported by reference numerals (#) of the drawings and the specification text (pg., ln) as follows:

1. An ultrasonic intracavity probe for scanning a volumetric region from within the body comprising:

a handle section {#36; pg. 4, ln 11-13} to be held during use of the probe; and

a shaft section {#32; pg. 4, ln 14-19} having a distal end which is to be inserted into a body cavity during use of the probe;

a pivotally mounted array transducer {#46; pg. 4, ln 19-29} located in a rigidly dimensioned compartment {#34, #40; pg. 4, ln 14-19; pg 6, ln 5-25} at the distal end of the shaft section;

a motor {#60; pg. 4, ln 29-32} located in the handle section;

a drive mechanism {#50; pg. 4, ln 29-32} coupled to the motor and the array transducer which acts to move the array transducer during scanning; and

a liquid bath constrained to the shaft section to the exclusion of the handle section and located in the compartment at the distal end of the shaft {pg. 6, ln 5-27}, a portion of which is located between the array transducer and the distal end of the shaft during scanning,

wherein the center of gravity of the probe is located in the handle section {pg. 6, ln 27-35}.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 1 and 2 were properly rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 5,178,150 (Silverstein et al.).

B. Whether Claims 4-10 were properly rejected under 35 U.S.C. §103(a) as unpatentable over Silverstein et al. and further in view of US Pat. 6,039,694 (Larson et al.)

C. Whether Claims 11-16 were properly rejected under 35 U.S.C. §103(a) as unpatentable over Silverstein et al. and further in view of US Pat. 6.315.710 (Bushek et al.)

D. Whether Claims 17-20 were properly rejected under 35 U.S.C. §103(a) as unpatentable over Silverstein et al. in view of Bushek et al. and further in view of US Pat. 6,621,065 (Fukumoto et al.)

VII. ARGUMENT

A. Whether Claims 1 and 2 were properly rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 5,178,150 (Silverstein et al.).

Amended Claim 1 describes an ultrasonic intracavity probe for scanning a volumetric region from within the body comprising a handle

section to be held during use of the probe; a shaft section having a distal end which is to be inserted into a body cavity during use of the probe; a pivotally mounted array transducer located in a rigidly dimensioned compartment at the distal end of the shaft section; a motor located in the handle section; a drive mechanism coupled to the motor and the array transducer which acts to move the array transducer during scanning; and a liquid bath constrained to the shaft section to the exclusion of the handle section and located in the compartment at the distal end of the shaft, a portion of which is located between the array transducer and the distal end of the shaft during scanning, wherein the center of gravity of the probe is located in the handle section. As is commonly known, when an ultrasonic imaging probe has a transducer which is swept or oscillated inside the probe to scan a body, an acoustic coupling liquid must be located between the transducer and the surrounding acoustic window of the probe to couple ultrasound between the acoustic window and the transducer, as ultrasound does not travel through air without severe attenuation. The common way to do this is to immerse the moving transducer in a liquid such as mineral oil or water. But a liquid is heavy and adds weight to the probe, a problem which is compounded when the probe is an elongated probe such as an intracavity probe. In that case, the liquid not only adds weight but, by the necessity of being at the end of the

probe where the transducer is located, undesirably shifts the center of gravity toward the distal (transducer) end of the probe, making the probe more difficult to manipulate and control. The problem is further compounded when the probe is designed for 3D imaging, as a 3D imaging array transducer must be used and not the smaller single piston or annular array transducers which are used in 2D imaging. As stated at the bottom of page 5 of the specification, some of the probes of the prior art such as the one described in the Silverstein et al. patent locate the liquid couplant in an elastomeric bag, which is bulky (col. 5, line 64 of Silverstein et al.) and can tear or rupture, posing a hazard to the patient in whose body the probe is used. The present inventors have overcome these obstacles by confining the liquid to a rigidly dimensioned compartment in the shaft of an intracavity probe where it provides acoustic coupling between the array transducer and the acoustic window at the distal end of the probe, and still keeps the center of gravity in the handle of the probe. Confining the liquid to the shaft also avoids complications of the liquid passing around or through the motor of the probe in the handle section of the probe, and the rigid compartment is not subject to tearing or rupture and thus does not pose a hazard to the patient.

The Examiner contends that Silverstein et al. shows a pivotally mounted array transducer (52) located in a rigidly dimensioned liquid-filled compartment. This contention is flatly wrong. The abstract of Silverstein et al. states:

> A flexible bag [62] filled with an acoustic coupling fluid is mounted at the distal end of the catheter. The bag surrounds the transducer body [50] to isolate it from the external environment and retain the acoustic coupling fluid. When the probe is to be inserted through a narrow passage the proximal actuating rod [54] is advanced into the catheter to extend the transducer body against the flexible bag. As a result, **the bag elongates and its width is reduced**. When the probe is to be used for imaging, the proximal actuating rod is retracted to withdraw the transducer body away from the bag and **allow the bag to expand radially**…."

As this description plainly states, the liquid compartment is not "rigidly dimensioned" as stated in Claim 1 of the present application. To the contrary, Silverstein et al. wants the bag to stretch and contort as the catheter is manipulated through the body and used for scanning. The Examiner is trying to contort the transducer body [50] into a rigidly dimensioned compartment for the liquid, which it is not. As the drawings show, the transducer body is inside the liquid-filled bag and surrounded by liquid. The cross-sectional view of Fig. 2 shows that the transducer body is solid inside except for a narrow lumen through which the wires to the transducer [52] extend, and the lumen is sealed to prevent intrusion of

the acoustic coupling fluid. For this first reason it is respectfully submitted that Silverstein et al. cannot anticipate Claims 1 and 2.

The Examiner also argues that since the distal end of the Silverstein et al. probe is a hollow actuating rod and the distal end is proportionally smaller than the handle, it is clear that the center of gravity of the probe is in the handle. But Fig. 2 of Silverstein et al. shows that the only hollow space in the actuating rod is the small lumen for the transducer wires, which is filled by the cable for the transducer. Figs. 3A and 3B show that the distal transducer mount 50 is in fact larger than the actuating rod 54. But the overarching fact is that none of the drawings show the full length of the shaft of the probe, the insertion tube 32. In every drawing its length is shown in a broken view. Hence, the assertion that the center of gravity of the probe is in the handle is pure speculation and not supported by the description in Silverstein et al. It is respectfully submitted that Claims 1 and 2 cannot be anticipated by Silverstein et al. for this further reason.

Furthermore the Examiner has acknowledged that the Silverstein et al. probe is a two-dimensional imaging probe which only scans a single plane within the body, not a volumetric region as recited in the claim. In this regard, Silverstein et al. does not have a pivotally mounted array transducer as called for by Claim 1, but only a single piston transducer

which can only scan a radial plane as it is rotated. For all of these reasons it is respectfully submitted that Silverstein et al. cannot anticipate Claim 1 and its dependent Claim 2.

B. Whether Claims 4-10 were properly rejected under 35 U.S.C. §103(a) as unpatentable over Silverstein et al. and further in view of US Pat. 6,039,694 (Larson et al.)

The Examiner's presumption that the subject matter of the claims of this application was commonly owned at all relevant times is correct.

Claims 4-10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Silverstein et al. in view of US Pat. 6,039,694 (Larson et al.) Larson et al. describe various hydrogel sheaths which provide acoustic coupling and a microbial barrier when slipped over the exterior of an ultrasound probe. Larson et al. does not show or suggest a liquid couplant bath or compartment, but solid hydrogel sheets. See col. 4, lines 28-66 of the Larson et al. patent. Larson et al. is unconcerned with the design of a fluid-filled probe. Thus, Larson et al. does not show or suggest any of the missing items of Silverstein et al. with respect to Claim 1. Larson et al. describe none of the liquid bath characteristics described in Claims 5-10. For these reasons it is respectfully submitted that Claim 1 and its dependent Claims 4-10 are patentable over the combination of Silverstein et al. and Larson et al.

C. Whether Claims 11-16 were properly rejected under 35 U.S.C. §103(a) as unpatentable over Silverstein et al. and further in view of US Pat. 6.315.710 (Bushek et al.)

Claims 11-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Silverstein et al. in view of US Pat. 6,315,710 (Bushek et al.) Bushek et al. describe an implantable hearing assistance device for the middle ear. The system of Bushek et al. is, like Larson et al., unconcerned with fluid-filled ultrasound probes and has nothing to do with motor-driven ultrasonic transducer assemblies. There is no basis for believing that a designer of ultrasound probes would look to implantable hearing aid devices for technical features. The Examiner contends that Bushek et al. teach a rotational transducer, but the rotation referred to is adjustment of the stops and barrel required to provide "precise positioning and contact" with the structure of the human ear. Once in place, nothing in the Bushek et al. ear implant moves. Even if Bushek et al. were relevant prior art, it still provides none of the Claim 1 elements missing from Silverstein et al. as described above. For these reasons it is respectfully submitted that the combination of Silverstein et al. and Bushek et al. cannot render Claim 1 or its dependent Claims 11-16 unpatentable.

D. Whether Claims 17-20 were properly rejected under 35 U.S.C. §103(a) as unpatentable over Silverstein et al. in view of Bushek et al. and further in view of US Pat. 6,621,065 (Fukumoto et al.)

Claims 17-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Silverstein et al. in view of Bushek et al. and further in view of US Pat. 6,621,065 (Fukumoto et al.) Fukumoto et al. is concerned with an optical CCD camera for a testing system. Like Bushek et al., Fukumoto et al. is completely unrelated to a mechanically scanning ultrasound probe with a fluid compartment. The Fukumoto et al. patent provides none of the claim elements lacking in Silverstein et al. with respect to Claim 1. Since Bushek et al. and Fukumoto et al. are both unconcerned with fluid-filled probes or ultrasound, it is respectfully submitted that the combination of Silverstein et al., Bushek et al., and Fukumoto et al. cannot render amended Claim 1 unpatentable. Since Claims 17-20 all ultimately depend from Claim 1, it is respectfully submitted that Claims 17-20 are patentable over Silverstein et al., Bushek et al., and Fukumoto et al. by reason of this dependency.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 1 and 2 are not anticipated by Silverstein et al., and that Claims 4-20 are patentable over Scott et al. and Teboul, and that Claim 12 is

patentable over Silverstein et al., Larson et al., Bushek et al., and Fukumoto et al. Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection of these claims stated in the July 19, 2010 Office action being appealed.

Respectfully submitted,

DAVID BECKER ET AL.

By: /W. Brinton Yorks, Jr./
W. Brinton Yorks, Jr.
Reg. No. 28,923

W. Brinton Yorks, Jr.
Philips Electronics
22100 Bothell Everett Highway
P.O. Box 3003
Bothell, WA 98041-3003
(425) 487-7152
November 11, 2010

APPENDIX A: CLAIMS APPENDIX

The following Claims 1-2 and 4-20 are the claims involved in the appeal.

1. (previously presented) An ultrasonic intracavity probe for scanning a volumetric region from within the body comprising:

a handle section to be held during use of the probe; and

a shaft section having a distal end which is to be inserted into a body cavity during use of the probe;

a pivotally mounted array transducer located in a rigidly dimensioned compartment at the distal end of the shaft section;

a motor located in the handle section;

a drive mechanism coupled to the motor and the array transducer which acts to move the array transducer during scanning; and

a liquid bath constrained to the shaft section to the exclusion of the handle section and located in the compartment at the distal end of the shaft, a portion of which is located between the array transducer and the distal end of the shaft during scanning,

wherein the center of gravity of the probe is located in the handle section.

2. (original) The ultrasonic intracavity probe of Claim 1, further comprising a transducer mount assembly located in the distal end of the shaft section, the array transducer being pivotally mounted to the transducer mount assembly,

wherein the liquid bath is located within the transducer mount assembly.

3. (canceled)

4. (previously presented) The ultrasonic intracavity probe of Claim 2, wherein the transducer mount assembly has a proximal termination within one and one-half inches of the terminus of the distal end of the shaft section.

5. (original) The ultrasonic intracavity probe of Claim 4, wherein 90% of the liquid bath is contained within the transducer mount assembly.

6. (original) The ultrasonic intracavity probe of Claim 1, wherein the liquid bath has a volume of less than 25 cc of liquid.

7. (original) The ultrasonic intracavity probe of Claim 6, wherein the liquid bath has a volume of less than 10 cc of liquid.

8. (original) The ultrasonic intracavity probe of Claim 7, wherein the liquid bath has a volume of approximately 6 cc of liquid.

9. (original) The ultrasonic intracavity probe of Claim 1, wherein 90% of the liquid bath is located in the most distal 25% of the length of the shaft section.

10. (original) The ultrasonic intracavity probe of Claim 9, wherein the liquid bath has a volume of less than 10 cc of liquid.

11. (original) The ultrasonic intracavity probe of Claim 1, further comprising a transducer mount assembly having a main body and located in the distal end of the shaft section, the array transducer being pivotally mounted to the transducer mount assembly, the main body of the transducer mount assembly being formed of a material which is lighter than stainless steel.

12. (original) The ultrasonic intracavity probe of Claim 11, wherein the array transducer is pivotally mounted to the transducer mount assembly by a transducer cradle,

wherein the transducer cradle is made of a material which is lighter than stainless steel.

13. (original) The ultrasonic intracavity probe of Claim 12, wherein the transducer cradle includes a solid body located behind the

array transducer which displaces volume in the transducer mount assembly that would otherwise be occupied by liquid.

14. (original) The ultrasonic intracavity probe of Claim 12, wherein the transducer cradle is tapered so as to pass more easily through the liquid bath.

15. (previously presented) The ultrasonic intracavity probe of Claim 11, wherein the transducer mount assembly includes wear surfaces which are made of stainless steel.

16. (original) The ultrasonic intracavity probe of Claim 15, wherein the wear surfaces are part of the drive mechanism.

17. (original) The ultrasonic intracavity probe of Claim 11, wherein the weight of the probe is less than 400 grams.

18. (original) The ultrasonic intracavity probe of Claim 17, wherein the weight of the probe is less than 300 grams.

19. (original) The ultrasonic intracavity probe of Claim 18, wherein the weight of the probe is approximately 250 grams.

20. (original) The ultrasonic intracavity probe of Claim 18, wherein the only components of the shaft which are made of a material at least equal to the density of stainless steel are components of the drive mechanism.

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted in this case.

APPENDIX C: RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.